

JAN 13 2009

510(k) SUMMARY

K072971

**Topcon Corporation's
3D OCT-1000 Optical Coherence Tomography System**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Topcon Corporation
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Tokyo, Japan 174

Additional Correspondents:

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OR

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Washington, DC 20004
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Date Prepared: October 19, 2007

Name of Device and Name/Address of Sponsor

Topcon 3D OCT-1000 Optical Coherence Tomography System
Topcon Corporation
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174

Common or Usual Name

AC- Powered Ophthalmoscope

Classification Name

Ophthalmoscope; 21 C.F.R. 886.1570

Predicate Devices

Topcon Corporation's 3D OCT-1000 Optical Coherence Tomography System
Carl Zeiss Meditec, Inc., *STRATUSOCT*TM with Retinal Nerve Fiber Layer and
Macula Normative Database

Talia Technology, Ltd., RTA 5 & RTA Model E Retinal Thickness Analyzer
Talia Technology, Ltd., RTA Retinal Thickness Analyzer

Intended Use / Indications for Use

The Topcon 3D OCT-1000 is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy. The device is indicated for assessing the area, location, and measurement of retinal thickness, including in patients with retinal pathologies. In addition, the device is indicated to detect separation between identified retinal layers and surfaces, *i.e.*, retinal tissue layers.

Technological Characteristics

The Topcon 3D OCT-1000 for Measurement of Retinal Thickness uses optical coherence tomography, which relies upon interferometry of superluminescent diode light reflected from the fundus of the eye to obtain cross-sectional images of the retina. The Topcon 3D OCT-1000 for Measurement of Retinal Thickness is identical to the FDA-cleared Topcon 3D OCT-1000 (K063388), with the exception of the addition of a new software module allowing for the measurement of retinal thickness.

Performance Data

Topcon conducted performance testing demonstrating that from an analytical perspective, the device provides accurate measurements. Additional performance testing demonstrated that the accuracy of the measurements reported from the device correlate with measurements calculated using manually identified retinal boundaries in a population with healthy retinas and a population with diseased retinas. The performance data demonstrate that the Topcon 3D OCT-1000 for Measurement of Retinal Thickness is as safe and effective as the predicate devices, and thus, substantially equivalent.

Substantial Equivalence

The Topcon 3D OCT-1000 for Measurement of Retinal Thickness is as safe and effective as the cleared Topcon 3D OCT-1000 Optical Coherence Tomography System, the Carl Zeiss Meditec, Inc., *STRATUSOCT*[™] with Retinal Nerve Fiber Layer and Macula Normative Database, the Talia Technology, Ltd., RTA 5 & RTA Model E Retinal Thickness Analyzer, and the Talia Technology, Ltd., RTA Retinal Thickness Analyzer. The Topcon 3D OCT-1000 for Measurement of Retinal Thickness has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences between the 3D OCT-1000 for Measurement of Retinal Thickness and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Topcon 3D OCT-1000 for Measurement of Retinal Thickness is as safe and effective as the predicate devices. Thus, the 3D OCT-1000 for Measurement of Retinal Thickness is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

JAN 13 2009

TopCon Medical Systems, Inc.,
c/o Jonathan Kahan
Partner
Hogan & Hartson, LLP
Columbia Square
5555 Thirteen St, NW
Washington, DC 20004

Re: K072971
Trade Name: TopCon 3D OCT-1000 for Measurement of Retinal Thickness
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: December 19, 2008
Received: December 19, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072971

Device Name: TOPCON 3D OCT-1000 for Measurement of Retinal Thickness

Indications For Use:

The Topcon 3D OCT-1000 is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in vivo viewing, axial, cross-sectional and three-dimensional imaging and measurements of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior segment of the eye.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

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